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#4

Form PTO-1390-MOD (REV 10-96)		U. S. Department of Commerce Patent and Trademark Office	ATTORNEY'S DOCKET NUMBER 4-32567A
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/518,575
INTERNATIONAL APPLICATION NO. PCT/EP03/007111	INTERNATIONAL FILING DATE July 3, 2003	PRIORITY DATE CLAIMED July 4, 2002	
TITLE OF INVENTION MARKER GENES FOR DETERMINING RENAL TOXICITY			
APPLICANT(S) FOR DO/EO/US CHIBOUT, ET AL.			

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau. (See Form PCT/IB/308)
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An executed Declaration and Power of Attorney (original or copy) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included.

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.  
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:

The following fees are submitted:				<b>CALCULATIONS</b> PTO USE ONLY	
21.	Basic national fee. ....	\$			
22.	Examination Fee If International preliminary examination report was prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) .....	\$			
	All other situations. ....	\$			
23.	Search fee If Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority. .... If International Search Report was prepared and provided to the Office. ... All other situations. ....	\$ \$ \$			
<b>TOTAL OF 21, 22 AND 23 =</b>			\$		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$      for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		X \$	\$	
Surcharge of \$130 for furnishing the oath of declaration later than <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	130
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =		X \$	\$	
Independent claims	- 3 =		X \$	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$	\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	130
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				\$	
<b>SUBTOTAL =</b>				\$	130
Processing fee of \$      for furnishing the English translation later than <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				+	\$
<b>TOTAL NATIONAL FEE =</b>				\$	130
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$      per property				+	\$
<b>TOTAL FEES ENCLOSED =</b>				\$	130
08/19/2005 GFREY1 00000078 190134 10518575				Amount to be: refunded	\$
01 EC:1617 130.00 DA				charged	\$

a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.

b. ☒ Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$130 to cover the above fees. A duplicate copy of this form is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis.

**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to the address associated with Customer No. 001095, which is currently:

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
Dated: ~~July~~ August 4, 2005

John T. Prince  
Attorney for Applicants  
Reg. No. 43,019  
(617) 871-3346



UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED  
JUL 1 2005

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/518,575	FIRST NAMED APPLICANT Salah-Dine CHIBOUT	ATTY. DOCKET NO. DC4-32567A
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INTERNATIONAL APPLICATION NO.
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PCT/EP03/07111

I.A. FILING DATE 07/03/2003	PRIORITY DATE 07/04/2002
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001095  
NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

JTP

CONFIRMATION NO. 7721  
371 FORMALITIES LETTER



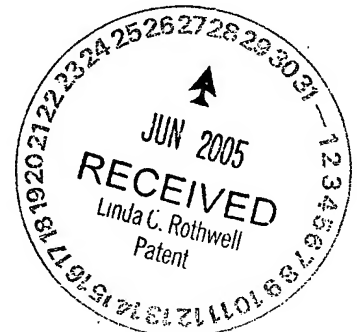
\*OC000000016318324\*

Date Mailed: 06/23/2005

**NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 12/22/2004
- Copy of the International Search Report filed on 12/22/2004
- Copy of IPE Report filed on 12/22/2004
- Preliminary Amendments filed on 12/22/2004
- U.S. Basic National Fees filed on 12/22/2004
- Priority Documents filed on 12/22/2004



The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

**SUMMARY OF FEES DUE:**

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Late oath or declaration Surcharge.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

DOCKETED FOR: Aug. 23, 2005

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

FRANCINE YOUNG

Telephone: (703) 308-9140 EXT 215

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/518,575	PCT/EP03/07111	DC4-32567A

FORM PCT/DO/EO/905 (371 Formalities Notice)